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BEST POSTERS AWARDS

THERAPEUTIC ANGIOGENESIS IN PATIENTS WITH SEVERE LIMB ISCHEMIA BY TRANSPLANTATION OF AN AUTOLOGOUS BONE MARROW-DERIVED COMBINATION STEM CELL PRODUCT

ACC Poster Contributions
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Background: Therapeutic angiogenesis using Endothelial Progenitor Cells (EPC) has emerged as a last resource to treat critical limb ischemia in patients without other revascularization options. We postulate that the use of a combination of stem/progenitor cells, instead of EPC alone, is more efficient for angiogenesis. In this phase II clinical study we infused critical limb ischemia patients with an autologous combination cell product (ACCP), containing a mixture of bone marrow-derived mononuclear cells (a source of EPC) and ex vivo expanded mesenchymal stem cells (MSC).

Methods: 26 subjects with critical limb ischemia were injected in the gastronemic muscle of the most ischemic leg with ACCP using a high and low dose protocol. Similarly, the contralateral leg was infused with a placebo product. Patients were followed-up (month 0.5, 1, 2, 4 and 12 post infusion) by assessing pain-free walking time, ankle brachial pressure index (ABI), 99mTc-TF perfusion scintigraphy and Quality of Life.

Results: Cell infusion was well tolerated. The ABI score of the treated legs increased as early as 1 month after cell infusion ($p \leq 0.05$). This effect persisted during the entire follow-up period. In all patients pain-free walking time increased during follow up. In each patient, the increase in pain free walking time correlated with a change in pain severity and relief. Perfusion scintigraphy (muscle-to-brain uptake, M/B ratios and planar images analysis) demonstrated increased perfusion in the treated group ($p \leq 0.03$). The favorable effects (ABI, walking time , Quality of Life and perfusion scintigraphy) elicited by ACCP in the treated legs demonstrated not to be cell dose-dependent and were not observed in the control legs. Healing or improvement of chronic arterial ulcers was observed in most patients.

Conclusion: Results of this phase II clinical trial show that the combination cell therapy used is safe and effective in reducing symptoms by promoting increase in blood flow in the treated ischemic leg of patients with critical limb ischemia as compared to placebo.